

### **CERTIFICATE OF** VALIDATION

Assurance of Structural Integrity

Product Number:

WAT062349

Product Name:

600 MultiSolvent Delivery Pump

Version Number:

Non-Applicable



**V** e assure that this product was developed, tested and validated using a System Development Life Cycle model. Product Life Cycle checkpoints were reviewed and approved by management. This product was found to meet performance specifications and release criteria as outlined in the Test Plan at the time of shipment.

To support this certificate for GLP and cGMP requirements of the user of this product, we will make the following documents available to customers, an authorized governmental or regulatory agency for inspection at Waters Corporation, Milford, Massachusetts:

- Marketing Requirements Definition
- Functional Specification
- Test Plan
- Test Summary Reports
- Source Code Documentation
- Revision Status
- Change Management Plan

Waters Corporation will maintain this documentation on-site or at a secure off-site location and will require a non-disclosure agreement to be provided by those wanting access to the information.

December 17, 1999

Date

Harvey Bloom, Director, Worldwide Quality

Vaters

Daniel McCormick, Vice President, Instrument Development

Virginia Corbin, Manager, Compliance Services



## INSTRUMENT OPERATIONS GROUP Waters Corporation

Certificate of Functional Performance

MODEL

2487 2-CHANNEL UV/VIS DETECT

A06487576M SERIAL#

Manufacturing

Approval

This is to certify that the stated instrument has successfully passed all quality and performance standards of WATERS CORPORATION.

## INSTRUMENT OPERATIONS GROUP Waters Corporation

Certificate of Functional Performance

MODEL

COLUMN HEATER COMPARTMENT

SERIAL#



Approval

Manufacturing \_

This is to certify that the stated instrument has successfully passed all quality and performance standards of WATERS CORPORATION.

## Waters Corporation

# INSTRUMENT OPERATIONS GROUP

Certificate of Functional Performance

Waters Fraction Collector III MODEL

SERIAL# L05WFC049M

Approval

Manufacturing

has successfully passed all quality and performance standards of WATERS CORPORATION. This is to certify that the stated instrument

## Waters Corporation

Certificate of Functional Performance

INSTRUMENT OPERATIONS GROUP

MODEL 600 PUMP, 0-20ML/MIN

SERIAL# L0560F934M



J. Approval

Manufacturing

This is to certify that the stated instrument has successfully passed all quality and performance standards of WATERS CORPORATION.

### INSTRUMENT OPERATIONS GROUP Waters Corporation

Certificate of Functional Performance

MODEL

REFRACTOMETER, 2414

SERIAL#

A06214498M

Manufacturing\_

Approval

This is to certify that the stated instrument has successfully passed all quality and performance standards of WATERS CORPORATION.



### **CERTIFICATE OF VALIDATION**

Assurance of Structural Integrity

Product Number:

WAT069520 & WAT069521

Product Name:

600E/600S Controllers

Version Number:

PowerLine V4.2



Vaters

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December 17, 1999

Date

Harvey Bloom, Director, Worldwide Quality

Alex Gliksberg, Director, Product and Process Engineering

Virginia Corbin, Manager, Compliance Services

WAT069588 Rev:1

Legal Identity:

Waters Corporation 34 Maple Street Milford, Mass. 01757 United States of America

**Authorized Representative:** 

Waters U.K. Limited Floats Road Wythenshawe

Manchester M2391Z United Kingdom

### **Equipment Identification**

Type of Equipment:

Laboratory - Liquid Chromatography

Model Number(s):

600 Contoller

We, Waters Corporation hereby declare that the devices mentioned above comply with the European In Vitro Diagnostic Directive 98/79/EC, Low Voltage Directive 73/23/EC & EMC Directive 89/336/EC

Common Technical Specifications used for demonstration of

compliance:

EN 61010-1:01, EN 61326-1:97 +A1:98 +A2:01,

EN 61010-2-101:02, EN ISO 9001: 2000,

Date of Validity:

March 30, 2004

Classification:

General IVDD

**Conformity Assessment Procedure:** 

IVDD Annex III

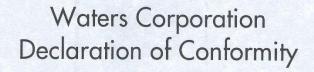
Name of Authorized Signatory: Position Held in Company Location @ signing

Signature:

Dave Terricciano

Vice President of Operations Milford, Massachusetts

716001403, Rev. A



Application of Council Directive(s): 73/23/EEC, 89/336/EEC

Standards to which conformity

Is declared:

EN61010-1, EN61326

Manufacturer's Name:

Manufacturer's Address:

Waters

34 Maple Street

Milford, MA 01757, USA

Type of Equipment:

Laboratory

Model:

Column Heater Module

I, the undersigned, hereby declare that the equipment specified conforms to the above Directives and Standards.

November 10, 2000

John Ornell

Vice President of Operations

Legal Identity:

Waters Corporation 34 Maple Street Milford, Mass. 01757 United States of America

**Authorized Representative:** 

Waters U.K. Limited Floats Road Wythenshawe Manchester M2391Z United Kingdom

**Equipment Identification** 

Type of Equipment:

Laboratory - Liquid Chromatography

Model Number(s):

2487 Dual  $\lambda$  Absorbance Detector

We, Waters Corporation hereby declare that the devices mentioned above comply with the European In Vitro Diagnostic Directive 98/79/EC, Low Voltage Directive 73/23/EC & EMC Directive 89/336/EC

**Common Technical Specifications** used for demonstration of

compliance:

EN 61010-1:01, EN 61326-1:97 +A1:98 +A2:01, EN 61010-2-101:02, EN ISO 9001: 2000,

December 10, 2003

Date of Validity: Classification:

General IVDD

**Conformity Assessment Procedure:** 

IVDD Annex III

Name of Authorized Signatory: Position Held in Company

Location @ signing

Dave Terricciano

Vice President of Operations Milford, Massachusetts

Signature:

716001282, Rev. A

Legal Identity:

Waters Corporation 34 Maple Street Milford, Mass. 01757 United States of America

**Authorized Representative:** 

Waters U.K. Limited Floats Road Wythenshawe

Manchester M2391Z United Kingdom

**Equipment Identification** 

Type of Equipment:

Laboratory - Liquid Chromatography

Model Number(s):

We, Waters Corporation hereby declare that the devices mentioned above comply with the European In Vitro Diagnostic Directive 98/79/EC, Low Voltage Directive 73/23/EC & EMC Directive 89/336/EC

Common Technical Specifications used for demonstration of

compliance:

EN 61010-1:01, EN 61326-1:97 +A1:98 +A2:01,

EN 61010-2-101:02, EN ISO 9001: 2000,

Date of Validity:

February 27, 2004

Classification:

General IVDD

**Conformity Assessment Procedure:** 

IVDD Annex III

Name of Authorized Signatory: Position Held in Company

Location @ signing

Dave Terricciano

Vice President of Operations Milford, Massachusetts

Signature:

716001289, Rev. B

Legal Identity:

Waters Corporation 34 Maple Street Milford, Mass. 01757 United States of America

**Authorized Representative:** 

Waters U.K. Limited Floats Road Wythenshawe

Manchester M2391Z United Kingdom

**Equipment Identification** 

Type of Equipment:

Laboratory - Liquid Chromatography

Model Number(s):

2414 Refractive Index Detector

We, Waters Corporation hereby declare that the devices mentioned above comply with the European In Vitro Diagnostic Directive 98/79/EC, Low Voltage Directive 73/23/EC & EMC Directive 89/336/EC

Common Technical Specifications

used for demonstration of

compliance:

EN 61010-1:01, EN 61326-1:97 +A1:98 +A2:01,

EN 61010-2-101:02, EN ISO 9001: 2000,

Date of Validity:

February 27, 2004

Classification:

General IVDD

**Conformity Assessment Procedure:** 

IVDD Annex III

Name of Authorized Signatory: Position Held in Company

Location @ signing

Dave Terricciano

Vice President of Operations Milford, Massachusetts

Signature:

716001290, Rev. A



### CERTIFICATE OF VALIDATION

Assurance of Structural Integrity

We assure that this product was developed, tested and validated using a System Development Life Cycle model. Product Life Cycle checkpoints were reviewed and approved by management. Product Number: 186241400 This product was found to meet performance specifications and release criteria as outlined in the Test Plan at the time of shipment. Version Number: To support this certificate for GLP and cGMP requirements of the user of this product, we will make the following documents 1.00 available to customers, an authorized governmental or regulatory agency for inspection at Waters Corporation, Milford, Massachusetts: Product Name: · Marketing Requirements Definition 2414 Refractive Index Detector Functional Specification Test Plan Test Summary Reports Source Code Documentation Revision Status Change Management Plan Waters Corporation will maintain this documentation on-site or at a secure off-site location and will require a non-disclosure agreement to be provided by those wanting access to the information. September 26, 2001

Waters

Daniel McCormick, Vice President, Instrument Development

Make H. Min

Date

Mark Robinson, Director, R & D Evaluation

Harvey Bloom, Director, Worldwide Quality



### CERTIFICATE OF VALIDATION

Assurance of Structural Integrity

Product Number:

WAT081110

Product Name:

2487 Dual λ Absorbance Detector

Version Number:

1.02

Y2K

Vaters

We assure that this product was developed, tested and validated using a System Development Life Cycle model. Product Life Cycle checkpoints were reviewed and approved by management. This product was found to meet performance specifications and release criteria as outlined in the Test Plan at the time of shipment.

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December 13, 2000

Date

Harvey Bloom, Director, Worldwide Quality

Clerander Jewsberg

Mak IL Min

Alex Gliksberg, Director, Product and Process Engineering

Mark Robinson, Manager, R & D Evaluation